

K041519

AUG - 4 2004

### 510(k) Summary

The following information is provided following the format of 21 CFR 807.92 for the On-Board Imager Device.

1. **Submitter:** Varian Medical Systems  
3100 Hansen Way M/S H055  
Palo Alto, CA 94304-1129  
Contact Name: Vy Tran  
Phone: (650) 424-5731  
Fax: (650) 842-5040  
Email: [vy.tran@varian.com](mailto:vy.tran@varian.com)  
Date summary was prepared: June 4, 2004

2. **Name of the Device:** **On-Board Imager**  
Trade/Proprietary Name: On-Board Imager Device  
Common or Usual Name: Imaging Accessory to Medical Linear Accelerator  
Classification Name: Medical Charged Particle Radiation Therapy  
System  
21 CFR §892.5050  
Class II  
Product Code: 90 IYE

3. Predicate Devices to claim substantial equivalence:  
a. Varian Medical Systems'On Board Imager, K040192

4. Device Description: The present device (K040192) is cleared to make corrections to a patient's position based on a comparison of the newly acquired digital kV X-ray images with digital reference images generated during treatment planning or simulation. Regarding this submission, the On-Board Imager has been modified to include correction of a patient's position based on comparison of fiducial markers in digital images to fiducial markers that are in reference 3-D volumetric data sets and allow for gated radiographic image acquisitions and fluoroscopic pretreatment visual verification.

5. Intended Use Statement: The On-Board Imager device is used for verification of correct patient position in relation to isocenter and verification of the treatment fields in relation to anatomical and/or fiducial landmarks.

6. Summary of the Technological Characteristics: The Substantial Equivalence Comparison Chart provides a comparison of the technological characteristics to those of the predicate devices. This chart is located in Tab 8 of the submission.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG - 4 2004

Ms. Vy Tran  
Corporate Director, Regulatory Affairs  
VARIAN Medical Systems, Inc.  
3100 Hansen Way  
PALO ALTO CA 94304-1038

Re: K041519

Trade/Device Name: On-Board Imaging Device  
Regulation Number: 21 CFR 892.5050  
Regulation Name: Medical charged-particle  
radiation therapy system

Regulatory Class: II  
Product Code: 90 IYE  
Dated: July 16, 2004  
Received: July 19, 2004

Dear Ms. Tran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

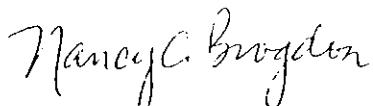
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K041519  
Device Name: On-Board Imager Device

Indications For Use:

The On-Board Imager Device is used for verification of correct patient position in relation to isocenter and verification of the treatment fields in relation to anatomical and/or fiducial landmarks.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Prescription Use          
(Per 21 CFR 801.109)

Nancy C Brogdon  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K041519